



BSI Standards Publication

Health informatics - Personal health device communication

Part 10425: Device specialization - Continuous glucose monitor (CGM)

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National foreword

This British Standard is the UK implementation of EN ISO 11073-10425:2019. It is identical to ISO/IEEE 11073-10425:2019.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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English Version

**Health informatics - Personal health device
communication - Part 10425: Device specialization -
Continuous glucose monitor (CGM) (ISO/IEEE 11073-
10425:2019)**

Informatique de santé - Communication entre
dispositifs de santé personnels - Partie 10425:
Spécialisation du dispositif - Glucomètre continu
(CGM) (ISO/IEEE 11073-10425:2019)

Medizinische Informatik - Kommunikation von Geräten
für die persönliche Gesundheit - Teil 10425:
Gerätespezifikation - Kontinuierlicher Glukose-Monitor
(ISO/IEEE 11073-10425:2019)

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This second edition cancels and replaces the first edition (ISO/IEEE 11073-10425:2016), which has been technically revised.

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Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of the communication between continuous glucose monitor (CGM) devices and managers (e.g., cell phones, personal computers, personal health appliances, set top boxes), in a manner that enables plug-and-play interoperability, is established in this standard. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology and information models. It specifies the use of specific term codes, formats, and behaviors in telehealth environments, restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality of CGM devices. In this context, CGM refers to the measurement of the level of glucose in the body on a regular (typically 5 minute) basis through a sensor continuously attached to the person.

Keywords: continuous glucose monitor, IEEE 11073-10425™, medical device communication, personal health devices

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Introduction

This introduction is not part of IEEE Std 11073-10425-2017, Health informatics—Personal health device communication—Part 10425: Device Specialization—Continuous Glucose Monitor (CGM).

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in ISO/IEEE 11073-20601:2016 and describes a specific, interoperable communication approach for continuous glucose monitors (CGMs).¹ These standards align with, and draw on, the existing clinically focused standards to provide support for communication of data from clinical or personal health devices (PHDs).

¹ Information on references can be found in Clause 2.

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Health informatics—Personal health device communication

Part 10425: Device Specialization— Continuous Glucose Monitor (CGM)

1. Overview

1.1 Scope

This standard establishes a normative definition of communication between personal health continuous glucose monitor (CGM) devices (agents) and managers (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability. It leverages work done in other ISO/IEEE 11073 standards including existing terminology, information profiles, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments, restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality of CGM devices. In this context, CGM refers to the measurement of the level of glucose in the body on a regular (typically 5 minute) basis through a sensor continuously attached to the person.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices (PHDs) and compute engines (e.g., cell phones, personal computers, personal health appliances, set top boxes). Interoperability is the key to growing the potential market for these devices and to enabling people to be better informed participants in the management of their health.

1.3 Context

See ISO/IEEE 11073-20601:2016 for an overview of the environment within which this standard is written.²

This standard defines the device specialization for the CGM, being a specific agent type, and it provides a description of the device concepts, its capabilities, and its implementation according to this standard.

² Information on references can be found in Clause 2.